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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/828,413 | 04/06/2001 | Robert H. DeBellis | 59469/JPW/SHS/MVM | 5162 |

7590 12/20/2004

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| EXAMINER | |
|---|---|
| SAUCIER, SANDRA E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/828,413 | DEBELLIS ET AL. | |
| | Examiner | Art Unit | |
| | Sandra Saucier | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10/21/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,10 and 14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,14,15 and 17-19* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1, 10, 14-19 are pending and under examination. The elected species is acylovir and the examiner has rejoined valacylovir as an extra species as explained in the office action of 2/12/04. The generic claim is not allowable. The species examination was extended by the examiner as a courtesy to the applicant to include valacyclovir as mentioned in the office action of 2/12/04. As a further courtesy, newly inserted species of famciclovir, penciclovir and ribavirin have also been searched.

### *Claim Rejections - 35 USC § 102*

Claims 1, 10, 14, 15, 17-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chinowsky [U].

The claims are directed to a one step method of treatment of a subject with sickle cell disease comprising administering an amount of an antiviral agent such as acyclovir effective to prevent sickling to treat the sickle cell disease.

Chinowsky discloses a one step administration of acyclovir in a patient with sickle cell hemoglobin C disease.

Claims 1, 10, 14, 17-19 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by De Castro *et al.* [V].

De Castro *et al.* disclose the one step method of administering ribavirin to a patient with sickle cell disease.

Because the patient is the same, namely a person afflicted with sickle cell disease, the compound administered is the same, acyclovir or ribavirin and the amount administered falls within the ranges given in the specification on page 7 for an oral dosage as being an effective dose, the result of the treatment must necessarily, inherently be the same.

It is not relevant to the analysis of the claimed method that the reference makes no mention of (inhibiting, preventing etc.). Discovery of a new benefit for an old process does not render the old process patentable. In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

See also *In re* Cruciferous Sprout 64 USPQ2d 1202 Fed. Circuit, where the Federal Circuit upheld a decision that patents licensed to Brassica Protection Products, Inc. are invalid because they are anticipated by the prior art. The patents are for method of growing and eating certain sprouts to reduce the level of carcinogens in animals, thereby reducing the risk of developing cancer. Prior art references disclose growing and eating those specific sprouts. The Federal Circuit cited authority for the rule that "a prior art reference may anticipate when the claim limitations not expressly found in the that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about (eating) those sprouts, it simply has not invented anything new.".

See also Ex parte Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of P. cepacia. A US patent to Dart disclosed inoculation using P. cepacia bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Response to Arguments*

Applicant's arguments filed 11/17/03 have been fully considered and are persuasive. The rejection over Lawson *et al.* has been withdrawn.

### *Allowable Subject Matter*

Claim 16 is still directed to allowable subject matter. Also, inclusion of penciclovir and famciclovir in the method claim would also be directed to allowable subject matter. The following claim is allowable.

1. A method of treating a subject afflicted with sickle cell disease which comprises administering to the subject an amount of an antiviral agent effective to inhibit sickling of a cell in the subject so as to thereby treat the subject, where the antiviral agent is valaciclovir, penciclovir or famciclovir.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) -272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor is M. Wityshyn. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
December 13, 2004